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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------------|------------------|
| 10/705,566   | 11/11/2003  | Hans-Jurgen Wachter  | Heraeus 412-WCG                    | 4253             |
| 27384 7590 01/17/2007<br>NORRIS, MCLAUGHLIN & MARCUS, PA<br>875 THIRD AVENUE<br>18TH FLOOR<br>NEW YORK, NY 10022 |             |                      | EXAMINER<br>KESSLER, CHRISTOPHER S |                  |
|  |             |                      | ART UNIT                           | PAPER NUMBER     |
|  |             |                      | 1742                               |                  |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 01/17/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/705,566

Applicant(s)

WACHTER ET AL.

Examiner

Christopher Kessler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-14 is/are rejected.
- 7) ☒ Claim(s) 8 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 December 2006 has been entered.

### ***Claim Objections***

2. Claims 8 and 9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim *should refer to other claims in the alternative only*. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5-7, 10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 6,767,360 issued to Alt et al. (hereinafter "Alt").

Regarding claim 1, Alt discloses the invention substantially as claimed. Alt discloses a niobium alloy for a medical device comprising preferably less than 1% zirconium, remainder niobium (see col. 4, lines 25-50). The compositional range significantly overlaps the range claimed by applicant, thus establishing a prima facie case of obviousness for that range (see MPEP §2144.05). It would have been obvious to one of ordinary skill in the art to have selected the claimed compositional range because Alt teaches the same utility over the entire range.

Regarding claim 2, Alt is applied to the claim as stated above.

Regarding claim 3, Alt is applied to the claim as stated above.

Regarding claim 5, Alt discloses wherein the medical device is a stent (see abstract, for example), meeting the limitation of being intra-cavernous.

Regarding claim 6, Alt discloses wherein the medical device is a stent (see abstract, for example), meeting the limitation of being an intravascular implant

Regarding claim 7, Alt discloses wherein the medical device is a stent (see abstract, for example).

Regarding claim 10, Alt discloses wherein an oxidation process passivates the stent (see col. 8, lines 16-44, for example).

Regarding claim 12, Alt discloses wherein the stent is sintered (see col. 6, lines 31-47, for example).

Regarding claim 13, Alt discloses wherein the stent is coated with a layer of niobium oxide (see col. 8, lines 16-44, for example).

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5. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claims 1-3 above, and further in view of U.S. Patent 6,387,121 issued to Alt (hereinafter "Alt '121").

Regarding claim 11, Alt does not disclose wherein the surface of the metal alloy is coated by iridium oxide by vapor deposition.

Alt '121 discloses a coated stent for vascular and endoluminal applications. Alt '121 clearly teaches that a layer of iridium oxide is coated onto the stent (see SUMMARY OF THE INVENTION, for example). It would have been obvious to one of ordinary skill in the art at the time of invention to alter the invention of Alt by coating the stent with iridium oxide, as taught by Alt '121 (cited above), in order to provide a means to deliver drugs to preclude thrombosis, as taught by Alt '121 (see SUMMARY OF THE INVENTION, for example).

Regarding claim 14, Alt does not disclose wherein the surface of the metal alloy is coated with stem cells and or a bioactive substance.

Alt '121 teaches that a stent is coated with iridium oxide to act as a carrier for beneficial drugs (see SUMMARY OF THE INVENTION, for example). It would have been obvious to one of ordinary skill in the art at time of invention to alter the invention of Alt by coating the stent with a beneficial drug, as taught by Alt '121 (cited above), in order to preclude occlusion from restenosis or thrombosis (see SUMMARY OF THE INVENTION).

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6. Claims 1, 2, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,845,259 issued to Pacetti et al. (hereinafter "Pacetti"), in view of Alt.

Regarding claim 1, Pacetti teaches that a guide wire is made from a niobium alloy in order to allow the guide wire to appear in MRI (see SUMMARY OF THE INVENTION, for example). Pacetti does not disclose wherein the alloy is a niobium/zirconium alloy.

Alt discloses a niobium alloy for a medical device comprising preferably less than 1% zirconium, remainder niobium (see col. 4, lines 25-50). The compositional range significantly overlaps the ranges claimed by applicant, thus establishing a prima facie case of obviousness for that range (see MPEP §2144.05). It would have been obvious to one of ordinary skill in the art to have selected the claimed compositional range because Alt teaches the same utility over the entire range. Alt further teaches a balloon angioplasty procedure, and it is well known in the art to install a stent *in vivo* through use of a guide wire during a balloon angioplasty (see col. 1, lines 32-51, for example).

It would have been obvious to one of ordinary skill in the art at time of invention to alter the invention of Pacetti by using the specific niobium alloy disclosed in Alt (cited above), in order to make a guide wire that would not distort the magnetic resonance field, as taught by Alt (see col. 2, lines 30-50).

Regarding claim 2, Pacetti and Alt are applied to the claim as stated above.

Regarding claim 3, Pacetti and Alt are applied to the claim as stated above.

Regarding claim 4, Pacetti and Alt are applied to the claim as stated above.

***Response to Arguments***

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Applicant's arguments filed 22 December have been fully considered but they are not persuasive. Applicants have stated that the invention was made prior to the cited prior art, but there is no documentation to prove these statements. The rejections based on the Alt reference are in effect.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6,790,228.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Kessler whose telephone number is (571) 272-6510. The examiner can normally be reached on Mon-Fri, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

csk

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